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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,749	03/22/2005	In-San Kim	428.1051	8173

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EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/528,749

Applicant(s)

KIM ET AL.

Examiner

Ernst V. Arnold

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-5, 7 and 8 are pending.

Applicant's remarks filed on 10/06/06 have been carefully considered by the Examiner. The Examiner has carefully considered by the Declaration under 37 CFR 1.132.

Applicant's amendments have necessitated a new ground of rejection. Applicant has expanded the scope of claim 1 with the introduction of a Markush group, which was not previously presented. This action is FINAL.

Withdrawn rejections:

Claims 1-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (J. Craniofac. Surg. 2002 May 13(3), 465-75) in view of Liu (US 5,281,265).

Applicant has submitted a Declaration under 37 CFR 1.132 demonstrating that the prior art reference was not by another. The Examiner withdraws the rejection.

Claim 3 was rejected under 35 U.S.C. 112 second paragraph. Applicant has amended the claim to recite only biopolymers. The Examiner withdraws the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al. (US 2002/0071827 Pub. Date: 06/13/2002) in view of Liu (US 5,281,265).

Applicant claims a gel-type bone-filling composition for stimulating bone-formation and bone-consolidation comprising 1) 20 -80 weight% of mixture containing CaSO_4 (90-99 weight%) and one or more inorganic salts selected from the group consisting of CaCO_3 , MgCO_3 , $\text{CaCO}_3 \cdot \text{MgCO}_3$ (1 – 10 weight%); and 2) 80-20 weight% of viscous biopolymer.

Determination of the scope and content of the prior art
(MPEP 2141.01)

Petersen et al. teach a bone graft substitute composition consisting essentially of calcium sulfate, a mixing solution and a plasticizing substance and a bone graft composition comprising calcium sulfate, demineralized bone matrix, cancellous bone, a plasticizing substance and a mixing solution (Claims 1 and 16). The plasticizing substance can be various biopolymers such as various celluloses including carboxymethylcellulose and ethyl cellulose, as well as hyaluronic acid (Claims 4, 7, and 19). Peterson et al. teach making injectable, paste and putty compositions, which the Examiner interprets to read upon gel-type (see page 4, [0056] and 0058], for example). Petersen et al. teach a composition comprising about 80-120 parts by weight calcium sulfate and about 1 to about 40 parts by weight plasticizing agent (claim 23). Petersen et al. teach that the composition can contain 0.1-2 weight % sodium bicarbonate as well as other inorganic elements and inorganic salts thus establishing a guideline for the addition of carbonate salts (Page 2, [0019], page 4 [0051]).

Liu teaches the resorbable calcium sulfate surgical cements for use in medical applications such as orthopedic and maxillofacial surgeries and dental applications comprising a biocompatible filler component selected from the group consisting of calcium carbonate, magnesium carbonate and mixtures thereof (Claims 1, 15 and 16). Liu teaches the weight ratio of the fillers to the cementing components can be up to 4 to 1 (Column 4, lines 41-53). Liu states that biocompatible filler component is substantially

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inert thus establishing that CaCO_3 , MgCO_3 , $\text{CaCO}_3 \cdot \text{MgCO}_3$ are secondary inert ingredients in the cement composition; thus they are optional and not required for the cement to function (Column 4, lines 41-57; Column 5, line 35 and claims 15 and 16).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Peterson et al. do not expressly teach adding one or more inorganic salts selected from the group consisting of CaCO_3 , MgCO_3 , $\text{CaCO}_3 \cdot \text{MgCO}_3$ (1 – 10 weight%) to the composition.

Peterson et al. do not expressly teach adding 0.3-1 weight% CaCO_3 , 0.3-1 weight % MgCO_3 and 0.5-1 weight % $\text{CaCO}_3 \cdot \text{MgCO}_3$ to the composition.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add one or more inorganic salts selected from the group consisting of CaCO_3 , MgCO_3 , $\text{CaCO}_3 \cdot \text{MgCO}_3$, as suggested by Liu, to the composition of Petersen et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Petersen suggests the inclusion of inorganic elements and salts and Liu teaches that these carbonate fillers are inert with respect to the interaction between the cementing component and the setting component. The adjustment of particular working conditions

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(e.g., determining an appropriate amount of CaCO_3 , MgCO_3 , $\text{CaCO}_3 \cdot \text{MgCO}_3$ to add to the composition) is deemed merely a matter of routine optimization. It is the Examiner's position, in the absence of clear and convincing evidence to the contrary, that calcium sulfate renders obvious other hydrated forms of calcium sulfate.

It is the Examiner's position that in the absence of any criticality/unexpected results, the presently claimed invention is considered *prima facie* obvious over the prior art for the reasons of record and those stated above.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

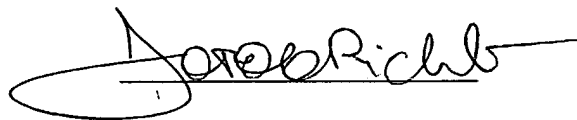
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
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A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning and a horizontal line extending from the end.

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600